

MAR 1 - 2005

K 043398

## Appendix G

### 510(k) Summary

<b>Submitter:</b>	NeoMetrics, Inc. 14800 28 <sup>th</sup> Ave. N., Suite 150 Plymouth, MN 55447
<b>Contact Person:</b>	Gene Champeau President 763-559-4440 (voice) 763-559-7676 (fax)
<b>Date Prepared:</b>	December 8th, 2004
<b>Trade Name:</b>	VascuPuncture™ PICC Guidewire
<b>Classification Name and Number:</b>	Wire, Guide, Catheter: 21 CFR 870.1330
<b>Product Code:</b>	DQX
<b>Predicate Device Name and 510(k) Number</b>	VascuPuncture PICC Guidewire, K031652 and K040786
<b>Device Description:</b>	<u>DEVICE DESCRIPTION</u> The VascuPuncture™ PICC Guidewires are guidewires constructed of stainless steel and nickel titanium alloy with a lubricious coating. Devices are available in diameters of 0.014 to 0.018 inches and in lengths ranging from 45 to 135 cm.
<b>Intended Use:</b>	The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. VascuPuncture Guidewires are not indicated for use in the coronary or cerebral vasculature.
<b>Statement of Technological Comparison</b>	Functional and performance characteristics are demonstrated through equivalence with the predicate device and testing of representative device samples. Biocompatibility is demonstrated through equivalence with legally marketed predicate devices and the result of ICPMS and prior biocompatibility testing.
<b>Conclusion:</b>	VascuPuncture™ PICC Guidewire with a tungsten or gold plated tungsten is substantially equivalent to the VascuPuncture™ PICC Guidewire. This conclusion is based upon the fact that this device is substantially equivalent to the predicate devices in terms of functional design, indications for use, principles of operation and performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 1 - 2005

Mr. Gene Champeau  
President  
NeoMetrics, Inc.  
14800 28<sup>th</sup> Ave. N., Suite 150  
Plymouth, MN 55447

Re: K043398  
Trade/Device Name: VascuPuncture PICC Guidewire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II (two)  
Product Code: DQX  
Dated: December 8, 2004  
Received: December 10, 2004

Dear Mr. Champeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

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systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Bram D. Zuckerman*

 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): **K043398**

Device Name: **VascuPuncture™ PICC Guidewire**

Indications For Use:

The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique

Prescription Use **XXX**  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Cochran*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number **K043398**